



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Review of Product Identity and Human Health Assessment for the Reregistration Eligibility Document (RED) for Allium sativum or Garlic (Case No. 4007; HED Project No. 2-8R4007; DP Barcode D171428; I.D. No. 128827; Caswell No. 003D)

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2/13/92

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A. Identification of Active Ingredient

Garlic is the fresh or dehydrated bulb or cloves obtained from Allium sativum, a plant belonging to the lily family. Natural derivatives of garlic include essential oils, oleoresins, and extracts. One such derivative is finely ground garlic bulbs (known as garlic powder) and is commercially available for flavoring and seasoning. The proposed active ingredient (a.i.) is either a powder or a distilled extract from garlic cloves and is used to repel birds and insects in certain fruit, nut, and citrus trees, vegetables, vine crops, berries, grains, roses, flowers, and shrubs. Garlic is generally recognized as safe (GRAS) under 21 CFR 182.10 (spices and other natural seasonings and flavorings) and 182.20 (essential oils, oleoresins [solvent-free] and natural extractives [including distillates]) as affirmed in 184.1317 (garlic and its derivatives). No additional data is required. However, quality control procedures should be in place to ensure that the manufacturing process used to produce the subject compound ensures the absence of hazardous components or materials.



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B. Human Health Assessment

1. Toxicology Data Base

The potential risks, if any, to humans from both nondietary and dietary exposure are considered negligible because of the long history of use by humans as a food. Consequently, all toxicology data requirements have been waived. No additional data will be required.

2. Dietary Exposure

Residue chemistry data requirements were waived based on the lack of toxicology concerns for the subject compound. Consequently, HED would support an exemption from the requirements of a tolerance.

3. Occupational and Residential Exposure

Garlic is formulated in dust, liquid concentrate and granular formulations containing 5-24% garlic a.i. and 12-36% ground red pepper a.i. (Capsicum spp.). There is also a 100% garlic water a.i. liquid product. The dust formulations are applied at planting, two days prior to harvest or whenever needed to repel birds and the liquid formulations can be sprayed every 7 or 8 days as needed to repel insects.

The dust and granular formulations are applied using a shaker duster in a band over the top of seedlings, a granular applicator at time of seeding, or onto the foliage of crops prior to harvest. A minimum rate of 20 pounds per acre of the 5% garlic/12% pepper a.i. product is used at seeding and a rate of up to 50 pounds per acre of this product are used when fruits begin to color but 7 days prior to harvesting. The liquid formulations are diluted with water and applied to repel insects by ground or air to cover foliage. The 100% a.i. garlic water product is diluted at a ratio of 1 gallon of product to 10 gallons of water. The 24% garlic a.i./36% pepper a.i. is diluted 1 gallon product to 250-450 gallons of water. The label directions specify a minimum number of gallons per acre but fail to distinguish whether this statement is referring to product or diluted mix in the tank.

The label limitations specified in the use profile are as follows:

Dust Formulations

For the dust formulations the signal word is "CAUTION" and the standard label language for this signal word appears on the label. Additional precautionary statements appear on the side panels including "Not for human consumption. May cause eye and skin irritation. Avoid contact with eyes, skin, or clothing. If in eyes, flush with water for 15 minutes.

Consult a physician if irritation persists. If on skin, wash with soap and water."

Liquid Formulations

For the liquid formulations the signal word is "CAUTION" and the standard label language for this signal word appears on the label. "Not for human consumption. May cause eye and skin irritation. Avoid contact with eyes, skin, or clothing. If in eyes, flush with water for 15 minutes. Consult a physician if irritation persists. If on skin, wash with soap and water."

4. Human Risk Assessment

The potential risks, if any, to humans from both nondietary and dietary are considered negligible because of the long history of use by humans as a food. Based on the application methods and formulation types, the potential for dermal and inhalation exposure to the mixer/loader/applicator exist. In addition, the potential for post-application exposure may be significant for the foliar treatments applied prior to harvest. However, due to the lack of toxicological concerns OREB has no data or product labeling concerns at this time.